SM

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,093	09/09/2003	John Daly	DAVI125.001CP1	9969

20995 7590 06/18/2004

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/658,093	DALY, JOHN	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-106 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-106 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claim Construction

The instant claims are directed to nucleic acids and methods of using nucleic acids comprising the following structurally and functionally distinct elements:

A. A polynucleotide encoding a polypeptide.

B. An RNA element that modulates the stability of a transcript.

C. A site for introducing a nucleic acid element.

D. A protein destabilizing element.

E. A transcriptional control element.

F. A post-transcriptional control element.

G. A *cis*-acting regulatory element.

H. A gene expression-modulating element.

I. A test sequence suspected of containing a post-transcriptional control element.

J. A test sequence suspected of containing a *cis*-acting regulatory element.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 23-58, 68, 70 and 85-92, drawn to a nucleic acid comprising the following combinations of elements: AB, ABC, ABCE, classified in class 435, subclass 320.1.

II. Claims 23-58, 68 and 85-102, drawn to a nucleic acid comprising the following combinations of elements: AB, ABC, ABCD, classified in class 435, subclass 320.1.

III. Claims 67, 68 and 72, drawn to a nucleic acid comprising the following combinations of elements: AB, ABD, ABDE, classified in class 435, subclass 320.1.

IV. Claims 67, 68 and 93-102, drawn to a nucleic acid comprising the following combinations of elements: AB, ABD, ABCD, classified in class 435, subclass 320.1.

V. Claims 68, 70 and 71, drawn to a nucleic acid comprising the following combinations of elements: AB, ABE, ABEG, classified in class 435, subclass 320.1.

VI. Claims 68, 70 and 71, drawn to a nucleic acid comprising the following combinations of elements: AB, ABE, ABEJ, classified in class 435, subclass 320.1.

VII. Claims 68, 71 and 72, drawn to a nucleic acid comprising the following combinations of elements: AB, ABE, ABDE, classified in class 435, subclass 320.1.

VIII. Claim 69, drawn to a nucleic acid comprising the following combinations of elements: AEF, classified in class 435, subclass 320.1.

IX. Claim 69, drawn to a nucleic acid comprising the following combinations of elements: AIF, classified in class 435, subclass 320.1.

X. Claim 69, drawn to a nucleic acid comprising the following combinations of elements: ACF, classified in class 435, subclass 320.1.

XI. Claim 59, drawn to a genetically modified non-human organism comprising a construct according to Groups I or II, wherein said organism is an animal, classified in class 800, subclass 13.

XII. Claim 59, drawn to a genetically modified non-human organism comprising a construct according to Groups I or II, wherein said organism is a plant, classified in class 800, subclass 295.

XIII. Claims 1-22, 65, 73-81 and 83, drawn to a method of using a nucleic acid comprising the following combinations of elements: ABE, ABDE, classified in class 435, subclass 6.

XIV. Claims 1-22, 66 and 73-84, drawn to a method of using a nucleic acid comprising the following combinations of elements: ABE, ABEJ, classified in class 435, subclass 6.

XV. Claims 60, 81-84 and 103-106, drawn to a method of using a nucleic acid comprising the following combinations of elements: ABH, ABDH, classified in class 435, subclass 6.

XVI. Claims 61, 62 and 64, drawn to a method of using a nucleic acid comprising the following combinations of elements: AEF, ADEF, classified in class 435, subclass 6.

XVII. Claim 63, drawn to a method of using a nucleic acid comprising the following combinations of elements: AEI, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I/II *versus* III/IV *versus* V/VI/VII *versus* VIII *versus* IX *versus* X embrace nucleic acids comprising subcombinations of structurally and functionally distinct elements, wherein the subcombinations might be used together in a single subcombination. For example, Group II embraces the subcombination ABC, which can be used together with the subcombination ABD of Group IV in the combination ABCD. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, each of the inventions is disclosed as useful in alternative combinations. For example, the subcombination ABC is disclosed as useful in the combination ABCE (*i.e.*, Group I) and the subcombination ABD is disclosed as useful in the combination ABDE (*i.e.*, Group III) See MPEP § 806.05(d).

Inventions I *versus* II, III *versus* IV, and V *versus* VI *versus* VII are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinguished by the distinct combinations embraced by each group. For example, the combination ABCE is not disclosed as capable of use together with the combination ABCD, and each combination has a distinct mode of operation, function and effect arising from the presence of the unique element comprised by the distinct combinations.

The nucleic acids of Groups I-X are related to the transgenic non-human organisms of Groups XI and XII in that the organism can be produced using the nucleic acid. The transgenic organism is distinct from the nucleic acid, however, because they are physically and functionally distinct and nucleic acid can be used for processes other than production of the transgenic

organism, such as in *in vitro* assays as contemplated in the disclosure. Furthermore, patentability of the transgenic organism arises from the phenotypic characteristics of the organism; thus, patentability of the transgenic organism is not solely dependent upon the particulars of the nucleic acid or polypeptide comprised within the organism.

The transgenic non-human animal of Group XI is distinct from the transgenic plant of Group XII. Although the transgenic plant and transgenic animal might comprise the same nucleic acid, the mode of operation, function and effect of a plant is clearly different from the mode of operation, function and effect of an animal.

Inventions XIII/XIV *versus* XV *versus* XVI *versus* XVII embrace methods of using nucleic acids comprising distinct subcombinations of functional elements, wherein the subcombinations might be used together in a single combination. Inventions XIII *versus* XIV embrace methods of using distinct combinations of elements. As method claims are distinguished from one another based on the steps comprised in the method and the mode of operation, function and effect of a method step using a product is defined by the product used in the step, the instant method Groups are distinct for the reasons set forth above regarding the product claims.

Inventions V-VII are related to Inventions XIII and XIV, and Invention VIII is related to Invention XVI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each of the methods is directed to assaying the activity of a regulatory element; however, the

products could be used in any process of producing a protein (*e.g.,* recombinant expression for use in raising an antibody or for use as a standard in an assay). Therefore, the product as claimed can be used in a materially different process, and restriction among the product and process claims is proper.

Finally, the methods of groups XIII, XIV and XVI are unrelated to the products of Groups I-IV and IX-XII because the combinations to which the product claims are limited are not disclosed as capable of use in the methods. Likewise, the products of Groups I-XII are unrelated to the processes of Groups XV and XVII because the combinations to which the product claims are limited are not disclosed as useful in the methods.

Linked Inventions

Groups I-VII are linked by the subcombination AB as recited in claim 68.

Groups I and II are linked by the subcombination ABC recited in claim 23.

Groups III and IV are linked by the subcombination ABD recited in claim 67.

Groups V, VI and VII are linked by the subcombination ABE recited in claim 71.

Groups XIII and XIV are linked by the subcombination ABE recited in claim 1.

The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s) (*i.e.,* claims 1, 23, 67, 68 or 71). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

Thus, if Applicant elects to prosecute the subject matter of any of Groups I-VII and claim 68 is deemed allowable, then the subject matter of all of Groups I-VII will be examined together.

If Applicant elects to prosecute the subject matter of Groups I or II, and claim 68 is not deemed allowable but the subject matter of claim 23 is allowed, then Groups I and II will be rejoined. Likewise, if Applicant elects to prosecute the subject matter of Groups III or IV, and claim 68 is not deemed allowable but the subject matter of claim 67 is allowed, then Groups III and IV will be rejoined and if Applicant elects to prosecute the subject matter of Groups V, VI or VII, and claim 68 is not deemed allowable but the subject matter of claim 71 is allowed, then Groups V, VI and VII will be rejoined.

If Applicant elects to prosecute the method of Groups XIII or XIV and claim 1 is deemed allowable, then Groups XIII and XIV will be rejoined.

Groups I and II are further restricted to prosecution of either the RNA destabilizing element of claims 24, 42, 44 and 45 or the RNA stabilizing element of claims 29 and 43. The distinct inventions are directed to nucleic acids comprising RNA elements having mutually exclusive activities and therefore cannot be used together and have distinct modes of operation, function and effect. An election to prosecute Group I or Group II must include an election to prosecute either the RNA destabilizing element of claims 24, 42, 44 and 45 or the RNA stabilizing element of claims 29 and 43. The Groups are linked by the RNA element that modulates the stability of a transcript as recited in claim 23. Claim 23 will be examined according to its full scope and if claim 23 is deemed allowable, the subject matter of claims 24, 42, 44 and 45 will be rejoined with the subject matter of claims 29 and 43.

Groups XIII and XIV are further restricted to prosecution of a method wherein the activity of a transcriptional control element is a measure of a single cellular event selected from those set forth in claim 22. Each of the cellular events recited in claim 22 is a distinct function and effect, which distinguishes each method specifically directed to measuring said function and effect. An election to prosecution either of Groups XIII or XIV must include an election of a single cellular event from claim 22. The groups are linked by the generic cellular event of claim 21, which will be examined according to its full scope and if claim 21 is deemed allowable, the cellular events recited in claim 22 will be rejoined and examined together.

Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, or because each of the distinct Inventions comprise distinct elements and therefore cannot be searched coextensively, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Within Group I or II:

a) the distinct species of protein destabilizing elements set forth in claim 28;

b) the distinct species of nucleic acid destabilizing elements set forth in claims 42, 44 and 45;

c) the distinct species of nucleic acid stabilizing elements set forth in claim 43;

d) the distinct species of reporter proteins set forth in claims 46 and 49;

e) the distinct species of cis-acting regulatory elements set forth in claim 53; and

Within Group XIII or XIV

f) the distinct species of protein destabilizing elements set forth in claim 6.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. An election of Group I or II must include an election of a single species from (a), (d) and (e) above, and from (b) or (c) depending upon whether Applicant elects to prosecute the nucleic acid destabilizing element or stabilizing element (*Id.*). An election of

Group XIII or XIV must include an election of a single species of protein destabilizing element from claim 6.

Currently, claim 27 is generic to the species of (a); claim 24 is generic to the species of (b); claim 29 is generic to the species of (c); claim 30 is generic to the species of (d, claim 46) and claim 47 is generic to the species of (d, claim 49); claim 52 is generic to the species of (e); and claim 5 is generic to the species of (f).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

DAVID GUZO
PRIMARY EXAMINER